

## EXHIBIT B

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## Premarket Approval (PMA)



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Note: this medical device has supplements. The device description may have changed. Be sure to look at the supplements to get an up-to-date view of this device.

**Trade Name** MEDTRONIC(R) SYNCHROMED(TM) PUMP & INFUSION SYSTEM

**Classification Name** Pump, Infusion, Implanted, Programmable<sup>23</sup>

**Generic Name** Implanted Infusion Pump

**Applicant** MEDTRONIC INC.

**PMA Number** P860004

**Date Received** 02/03/1986

**Decision Date** 03/14/1988

**Product Code** LKK [[Registered Establishments With LKK](#)<sup>24</sup>]

**Docket Number** 88M-0114

**Notice Date** 05/11/1988

**Advisory Committee** General Hospital

**Expedited Review Granted?** No

**Combination Product** [Yes](#)<sup>25</sup>

### Recalls

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24. [/scripts/cdrh/cfdocs/cfRL/r1.cfm?start\\_search=1&establishmentName=&StateName=&CountryName=&RegistrationNumber=&OwnerOperatorNumber=&OwnerOperatorName=&ProductC](/scripts/cdrh/cfdocs/cfRL/r1.cfm?start_search=1&establishmentName=&StateName=&CountryName=&RegistrationNumber=&OwnerOperatorNumber=&OwnerOperatorName=&ProductC)
25. <http://www.fda.gov/CombinationProducts/default.htm>
26. [/scripts/cdrh/cfdocs/cfRES/res.cfm?start\\_search=1&pnumber=P860004](/scripts/cdrh/cfdocs/cfRES/res.cfm?start_search=1&pnumber=P860004)
27. [/scripts/cdrh/cfdocs/cfpma/pma.cfm?start\\_search=1&PMANumber=P860004&SupplementNumber=S001](/scripts/cdrh/cfdocs/cfpma/pma.cfm?start_search=1&PMANumber=P860004&SupplementNumber=S001)
28. [/scripts/cdrh/cfdocs/cfpma/pma.cfm?start\\_search=1&PMANumber=P860004&SupplementNumber=S002](/scripts/cdrh/cfdocs/cfpma/pma.cfm?start_search=1&PMANumber=P860004&SupplementNumber=S002)
29. [/scripts/cdrh/cfdocs/cfpma/pma.cfm?start\\_search=1&PMANumber=P860004&SupplementNumber=S003](/scripts/cdrh/cfdocs/cfpma/pma.cfm?start_search=1&PMANumber=P860004&SupplementNumber=S003)
30. [/scripts/cdrh/cfdocs/cfpma/pma.cfm?start\\_search=1&PMANumber=P860004&SupplementNumber=S004](/scripts/cdrh/cfdocs/cfpma/pma.cfm?start_search=1&PMANumber=P860004&SupplementNumber=S004)
31. [/scripts/cdrh/cfdocs/cfpma/pma.cfm?start\\_search=1&PMANumber=P860004&SupplementNumber=S005](/scripts/cdrh/cfdocs/cfpma/pma.cfm?start_search=1&PMANumber=P860004&SupplementNumber=S005)
32. [/scripts/cdrh/cfdocs/cfpma/pma.cfm?start\\_search=1&PMANumber=P860004&SupplementNumber=S006](/scripts/cdrh/cfdocs/cfpma/pma.cfm?start_search=1&PMANumber=P860004&SupplementNumber=S006)
33. [/scripts/cdrh/cfdocs/cfpma/pma.cfm?start\\_search=1&PMANumber=P860004&SupplementNumber=S007](/scripts/cdrh/cfdocs/cfpma/pma.cfm?start_search=1&PMANumber=P860004&SupplementNumber=S007)
34. [/scripts/cdrh/cfdocs/cfpma/pma.cfm?start\\_search=1&PMANumber=P860004&SupplementNumber=S008](/scripts/cdrh/cfdocs/cfpma/pma.cfm?start_search=1&PMANumber=P860004&SupplementNumber=S008)
35. [/scripts/cdrh/cfdocs/cfpma/pma.cfm?start\\_search=1&PMANumber=P860004&SupplementNumber=S010](/scripts/cdrh/cfdocs/cfpma/pma.cfm?start_search=1&PMANumber=P860004&SupplementNumber=S010)
36. [/scripts/cdrh/cfdocs/cfpma/pma.cfm?start\\_search=1&PMANumber=P860004&SupplementNumber=S011](/scripts/cdrh/cfdocs/cfpma/pma.cfm?start_search=1&PMANumber=P860004&SupplementNumber=S011)
37. [/scripts/cdrh/cfdocs/cfpma/pma.cfm?start\\_search=1&PMANumber=P860004&SupplementNumber=S012](/scripts/cdrh/cfdocs/cfpma/pma.cfm?start_search=1&PMANumber=P860004&SupplementNumber=S012)
38. [/scripts/cdrh/cfdocs/cfpma/pma.cfm?start\\_search=1&PMANumber=P860004&SupplementNumber=S013](/scripts/cdrh/cfdocs/cfpma/pma.cfm?start_search=1&PMANumber=P860004&SupplementNumber=S013)
39. [/scripts/cdrh/cfdocs/cfpma/pma.cfm?start\\_search=1&PMANumber=P860004&SupplementNumber=S014](/scripts/cdrh/cfdocs/cfpma/pma.cfm?start_search=1&PMANumber=P860004&SupplementNumber=S014)
40. [/scripts/cdrh/cfdocs/cfpma/pma.cfm?start\\_search=1&PMANumber=P860004&SupplementNumber=S016](/scripts/cdrh/cfdocs/cfpma/pma.cfm?start_search=1&PMANumber=P860004&SupplementNumber=S016)
41. [/scripts/cdrh/cfdocs/cfpma/pma.cfm?start\\_search=1&PMANumber=P860004&SupplementNumber=S017](/scripts/cdrh/cfdocs/cfpma/pma.cfm?start_search=1&PMANumber=P860004&SupplementNumber=S017)
42. [/scripts/cdrh/cfdocs/cfpma/pma.cfm?start\\_search=1&PMANumber=P860004&SupplementNumber=S019](/scripts/cdrh/cfdocs/cfpma/pma.cfm?start_search=1&PMANumber=P860004&SupplementNumber=S019)
43. [/scripts/cdrh/cfdocs/cfpma/pma.cfm?start\\_search=1&PMANumber=P860004&SupplementNumber=S020](/scripts/cdrh/cfdocs/cfpma/pma.cfm?start_search=1&PMANumber=P860004&SupplementNumber=S020)
44. [/scripts/cdrh/cfdocs/cfpma/pma.cfm?start\\_search=1&PMANumber=P860004&SupplementNumber=S022](/scripts/cdrh/cfdocs/cfpma/pma.cfm?start_search=1&PMANumber=P860004&SupplementNumber=S022)
45. [/scripts/cdrh/cfdocs/cfpma/pma.cfm?start\\_search=1&PMANumber=P860004&SupplementNumber=S023](/scripts/cdrh/cfdocs/cfpma/pma.cfm?start_search=1&PMANumber=P860004&SupplementNumber=S023)
46. [/scripts/cdrh/cfdocs/cfpma/pma.cfm?start\\_search=1&PMANumber=P860004&SupplementNumber=S024](/scripts/cdrh/cfdocs/cfpma/pma.cfm?start_search=1&PMANumber=P860004&SupplementNumber=S024)
47. [/scripts/cdrh/cfdocs/cfpma/pma.cfm?start\\_search=1&PMANumber=P860004&SupplementNumber=S026](/scripts/cdrh/cfdocs/cfpma/pma.cfm?start_search=1&PMANumber=P860004&SupplementNumber=S026)
48. [/scripts/cdrh/cfdocs/cfpma/pma.cfm?start\\_search=1&PMANumber=P860004&SupplementNumber=S027](/scripts/cdrh/cfdocs/cfpma/pma.cfm?start_search=1&PMANumber=P860004&SupplementNumber=S027)
49. [/scripts/cdrh/cfdocs/cfpma/pma.cfm?start\\_search=1&PMANumber=P860004&SupplementNumber=S028](/scripts/cdrh/cfdocs/cfpma/pma.cfm?start_search=1&PMANumber=P860004&SupplementNumber=S028)
50. [/scripts/cdrh/cfdocs/cfpma/pma.cfm?start\\_search=1&PMANumber=P860004&SupplementNumber=S029](/scripts/cdrh/cfdocs/cfpma/pma.cfm?start_search=1&PMANumber=P860004&SupplementNumber=S029)
51. [/scripts/cdrh/cfdocs/cfpma/pma.cfm?start\\_search=1&PMANumber=P860004&SupplementNumber=S030](/scripts/cdrh/cfdocs/cfpma/pma.cfm?start_search=1&PMANumber=P860004&SupplementNumber=S030)
52. [/scripts/cdrh/cfdocs/cfpma/pma.cfm?start\\_search=1&PMANumber=P860004&SupplementNumber=S031](/scripts/cdrh/cfdocs/cfpma/pma.cfm?start_search=1&PMANumber=P860004&SupplementNumber=S031)
53. [/scripts/cdrh/cfdocs/cfpma/pma.cfm?start\\_search=1&PMANumber=P860004&SupplementNumber=S032](/scripts/cdrh/cfdocs/cfpma/pma.cfm?start_search=1&PMANumber=P860004&SupplementNumber=S032)
54. [/scripts/cdrh/cfdocs/cfpma/pma.cfm?start\\_search=1&PMANumber=P860004&SupplementNumber=S033](/scripts/cdrh/cfdocs/cfpma/pma.cfm?start_search=1&PMANumber=P860004&SupplementNumber=S033)
55. [/scripts/cdrh/cfdocs/cfpma/pma.cfm?start\\_search=1&PMANumber=P860004&SupplementNumber=S034](/scripts/cdrh/cfdocs/cfpma/pma.cfm?start_search=1&PMANumber=P860004&SupplementNumber=S034)

## **Premarket Approval (PMA)**

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